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Test and Evaluation Report of the IVAC® Vital Check Monitor Model 4000AEE

By

James E. Bruckart (Project Officer)
and
Joseph R. Licina (Project Officer)

Bill Olding (UES, Inc.)
Martin Quattlebaum (UES, Inc.)

Biodynamics Research Division

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United States Army Aeromedical Research Laboratory
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Research Division

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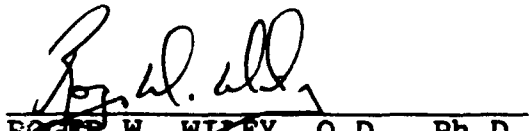

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The IVAC® Vital Check Monitor Model 4000AEE was tested for electromagnetic interference/compatibility in the UH-60A helicopter under the U.S. Army Program for Testing and Evaluation of Equipment for Aeromedical Operations. The tests were conducted using current military and industrial standards and procedures for electromagnetic interference/compatibility and human factors. The IVAC® Vital Check Monitor Model 4000AEE was found to be compatible with U.S. Army medical evacuation UH-60A Blackhawk. However, ambient noise levels in the helicopter prevented proper operation of the microphone in the blood pressure cuff which resulted in measurement errors.

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3. SUPPORTING DOCUMENTATION

Section 1. Executive digest

The Army program for Test and Evaluation of Aeromedical Equipment uses existing military standards (MIL-STD) and collective professional expertise to test and evaluate selected medical equipment proposed for use aboard Army aircraft. Equipment meeting these standards ensures the safety of the crew, patients, and aircraft by eliminating risks due to: (1) Interference by the medical equipment with aircraft systems/subsystems operation, (2) the aircraft system's interference with the operation of the medical equipment, (3) the medical equipment's susceptibility to environmental exposure, or (4) physical and/or functional incompatibility while in use on board selected rotary-wing aircraft. This program tests both developmental and nondevelopmental (off the shelf) medical equipment destined for use aboard Army medical evacuation aircraft.

1.1 TEST OBJECTIVES

1.1.1 To determine if the medical equipment is complete and operational per the manufacturer's operating instructions.

1.1.2 To ensure the electrical safety of the medical equipment.

1.1.3 To ensure the equipment will function as designed throughout the rated battery operation time.

1.1.4 To ensure the safety of the operator, the patient, and the aircrew.

1.1.5 To assess design considerations which potentially could contribute to an operator error.

1.1.6 To determine if the medical equipment can function as designed in a low pressure environment.

1.1.7 To determine the ability of the medical equipment to withstand the vibrational stresses expected in a rotary-wing flight environment without degradation or malfunction.

1.1.8 To determine the ability of the medical equipment to be stored and operated in a high-temperature environment.

1.1.9 To determine the ability of the medical equipment to be stored and operated in a low-temperature environment.

1.1.10 To determine the ability of the medical equipment to operate satisfactorily for short periods during exposure to high humidity conditions.

1.1.11 To assess the levels of electromagnetic emissions produced by the medical equipment within selected frequency ranges.

1.1.12 To assess the minimum electromagnetic susceptibility levels of the medical equipment within selected frequency ranges.

1.1.13 To assess the physical and/or functional compatibility of the medical equipment while in use on board the aircraft.

1.1.14 To assess the electromagnetic interference (EMI) and electromagnetic compatibility (EMC) characteristics of the medical equipment with the host aircraft and its installed systems.

1.2 TESTING AUTHORITY

Research and Technology Work Unit Summary, dated 5 October 1989. Project number 3M463807D836, titled, Army Program for Testing and Evaluation of Equipment for Aeromedical Operations.

1.3 SCOPE

1.3.1 This test was conducted at the United States Army Aeromedical Research Laboratory (USAARL), Cairns Army Airfield (CAAF), and designated test flight areas in and around Fort Rucker, Alabama.

1.3.2 The USAARL UH-60A aircraft, serial number 88-26069, with subsystems delineated in paragraph 3.2.2, was configured with the IVAC® Vital Check monitor*, model 4000AEE and used as the test aircraft for the in-flight evaluation. The in-flight evaluation required 2.1 flight hours.

1.3.3 Laboratory testing was accomplished at USAARL using government furnished equipment (GFE) by Universal Energy Systems, Inc. (UES), under contract No. DAMD 17-86-C-6215.

1.3.4 Prior to flight testing, the following tests were accomplished: Acceptance inspection, equipment training, electromagnetic compatibility, human factors and safety, environmental compatibility, and in-flight compatibility.

1.3.5 An airworthiness release (AWR) dated 12 Jul 1990 was received from the U.S. Army Aviation Systems Command (AVSCOM) prior to the in-flight testing of the IVAC® Model 4000AEE.

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* See list of manufacturers

1.4 MATERIAL DESCRIPTION

The IVAC® Model 4000AEE Vital Check monitor is a portable device designed to measure a patient's blood pressure (BP) and temperature. The front panel contains light emitting diodes (LED) displays that show the patient's systolic pressure, diastolic pressure, mean arterial pressure (MAP), pulse and temperature. The BP measurements may be initiated manually or automatically at timed intervals. A control knob on the front panel allows the user to select cuff pressures of 100, 125, 150, or 200 mmHg. A second control knob allows the user to select automatic BP measurements at 1-, 2.5-, 5-, 15-, or 30- minute intervals. The unit can recall up to 20 BP readings. The monitor will reinflate the cuff when it detects artifact, low signal intensity, or an unusually high BP reading. The unit provides a visual display of the Korotkoff sounds and is equipped with a stethoscope attachment to monitor the sounds. The visual display of the Korotkoff sounds is presented on the front panel under the pulse reading. The on/off and start/reset buttons are located under the control knobs on the front panel. A control switch on the rear panel selects whether temperature readings are displayed in Fahrenheit or Celsius. Audible beeps indicate when a new BP or predictive temperature has been reached.

1.5 SUMMARY

1.5.1 Laboratory testing

1.5.1.1 Battery life evaluation: The IVAC® Model 4000AEE was operated on a fully-charged battery with 2.5 minute measurement interval mode until a low battery indication light was noted and an audio alarm sounded. The fully-charged IVAC® Model 4000AEE averaged 7 hours and 13 minutes of operation (174 measurements). The monitor battery is rated for 2.5 hours of operation or 150 BP measurements. This exceeds the manufacturer's specification.

1.5.1.2 Electrical safety evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the IVAC® Model 4000AEE. The limits for currents and resistances were in accordance with (IAW) the National Association of Fire Prevention (NAFP) standards.

1.5.1.3 Human factors evaluation: The IVAC® Model 4000AEE was found to be satisfactory in all major categories of the evaluation criteria with one exception. The red light emitting diode displays do not have an intensity control.

1.5.1.4 Environmental tests: The IVAC® Model 4000AEE can be expected to perform in a variety of environmental conditions. Its performance was found to be satisfactory in all stages of the environmental testing. The requirements for environmental tests

are established in MIL-STD-810D, methods 500.2 (altitude), 514.3 (vibration), 501.2 (high temperature), 502.2 (low temperature), and 507.2 (humidity).

1.5.1.5 Radiated emissions tests (RE02): The IVAC® Model 4000AEE may be unsatisfactory for use in certain EMI sensitive environments. Narrowband (NB) and broadband (BB) radiated emissions were detected in the test frequency ranges. Some narrowband and broadband emissions exceeded the test limits. Emission limits are set forth in MIL-STD-461A, Notice 4.

1.5.1.6 Radiated susceptibility test (RS03): The IVAC® Model 4000AEE was found to be susceptible to radio frequency interference in the testing range and magnitude.

1.5.1.7 Conducted emissions test (CE01, CE02, and CE04): Conducted emissions were measured in the frequency range 19.033 to 41.898 MHz at levels 0.7 to 7.5 dB over specification limits.

1.5.1.8 Conducted susceptibility test (CS02 and CS06): No susceptibility to the test power line spikes was noted in the IVAC® Model 4000AEE.

1.5.2 In-flight testing

1.5.2.1 During the in-flight human factors evaluation, the IVAC® Model 4000AEE was found to be satisfactory in all categories of the evaluation criteria with two exceptions. The audible beeps could not be heard and there is no provision to vary the intensity of the LED display.

1.5.2.2 The aircraft and its subsystems were not adversely affected by the operation of the IVAC® Model 4000AEE in any of the prescribed flight test modes.

1.5.2.3 The ambient noise levels during ground operation and cruise flight prevented the cuff microphone from receiving valid Korotkoff sounds. This resulted in inaccurate BP and heart rate readings for 70 percent of the machine cycles during these phases of flight.

1.6 CONCLUSIONS

Based on the results of laboratory and in-flight testing, the IVAC® Model 4000AEE was found to be compatible with U.S. Army medical evacuation UH-60A Blackhawk with the subsystems listed in paragraph 3.2.2. Ambient noise levels in the helicopter prevented proper operation of the microphone in the BP cuff which resulted in measurement errors.

Section 2. Subtests

2.1 INITIAL INSPECTION

2.1.1 Objective

To determine if the IVAC® Model 4000AEE is complete and operational for testing per the manufacturer's operating instructions.

2.1.2 Criteria

2.1.2.1 The physical inventory is conducted solely for investigation and documentation.

2.1.2.2 The IVAC® Model 4000AEE will display consistent and accurate measurements as an acceptable performance test.

2.1.3 Test procedure

2.1.3.1 A complete physical inventory of the IVAC® Model 4000AEE was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the IVAC® Model 4000AEE was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

2.1.4 Test findings

2.1.4.1 The IVAC® Model 4000AEE was inventoried and found to be complete.

2.1.4.2 The IVAC® Model 4000AEE operated as prescribed in the manufacturer's operating manual P/N 120713 NC. Criteria met.

2.2 BATTERY LIFE EVALUATION (Laboratory)

2.2.1 Objective

To ensure the equipment will function as designed throughout the rated battery operation time.

2.2.2 Criterion

Verify manufacturer's specified full power internal battery life expectancy of 2.5 hours monitor operation or 150 BP measurements.

2.2.3 Test procedure

2.2.3.1 Charging and operation cycles were conducted in ambient room conditions.

2.2.3.2 The IVAC® Model 4000AEE was operated continuously using its fully-charged internal battery in the 2.5-minute cycle mode until a low battery indication occurred. The depletion time was noted and the battery was recharged. This procedure was repeated three times.

2.2.4 Test findings

The test was conducted using the fully-charged internal battery. The average operating time in testing was 7 hours and 31 minutes at room temperature. During this period, 174 BP measurements were completed. This exceeds manufacturer's specification of 30 minutes. Criterion met.

2.3 ELECTRICAL SAFETY EVALUATION

2.3.1 Objective

To ensure the electrical safety of the IVAC® Model 4000AEE by evaluation of case-to-ground resistance and case-to-ground current leakage.

2.3.2 Criterion

The IVAC® Model 4000AEE shall meet the standards established in NAFP 99 for electrical safety of medical equipment.

2.3.3 Test procedure

Measurements in the electrical safety evaluation were made with a Neurodyne-Dempsey model 431F electrical safety analyzer*, IAW the procedures described in Technical Bulletin (TB) Number 38-750-2. Case-to-ground resistance and various case-to-ground leakage currents were measured. Leakage currents were measured using a 10 by 20 centimeter aluminum foil sheet taped flush to the equipment case. Checks were made for safety concerns such as case integrity, breaks in power cord insulation, and connectors.

2.3.4 Test findings

Grounding conductor resistance was 69.3 milliohms and maximum case leakage current was 11.5 microamperes. These measurements are below the limits specified in NAFP 99. Criterion met.

2.4 HUMAN FACTORS EVALUATION (Laboratory)

2.4.1 Objectives

2.4.1.1 To assure the safety of the operator, the potential patient, and the aircrew.

2.4.1.2 To assess the design considerations which could potentially contribute to an operator error.

2.4.2 Criterion

The IVAC® Model 4000AEE must be rated satisfactory in all major categories of the evaluation. These include visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.4.3 Test procedure

2.4.3.1 The evaluation was conducted in a laboratory under fluorescent lighting and ambient room conditions.

2.4.3.2 The IVAC® Model 4000AEE was operated according to prescribed instructions through its full range of functions.

2.4.4 Test finding

The IVAC® Model 4000AEE was found to be satisfactory in all of the evaluation criteria with one exception. The red LED displays do not have an intensity control. Criterion partially met.

2.5 ALTITUDE (LOW PRESSURE) TEST [IAW MIL-STD-810D, METHOD 500.2]

2.5.1 Objective

To determine if the IVAC® Model 4000AEE can function as designed in a low-pressure environment.

2.5.2 Criterion

The IVAC® Model 4000AEE will display consistent and accurate measurements while exposed to an altitude equivalency of 15,000 feet above sea level.

2.5.3 Test procedure

2.5.3.1 A pretest performance check was conducted to ensure proper operation of the IVAC® Model 4000AEE.

2.5.3.2 The altitude test was performed in a Tenney Engineering model 64S altitude chamber*. This test is based on MIL-STD-810D, Method 500.2. The IVAC® Model 4000AEE was turned on in the standby mode and placed on the floor of the chamber. Chamber pressure was decreased to 420 mmHg (15,000 ft equivalent altitude) over a 15-minute period, held constant for 60 minutes, then raised, at 1500 fpm, to ambient conditions (760 mmHg) over a 10-minute period. There were no provisions for the control of temperature or humidity inside this chamber.

2.5.3.3 A posttest performance check was conducted to ensure proper operation of the IVAC® Model 4000AEE after the exposure to low pressure.

2.5.4 Test findings

2.5.4.1 The pretest performance check met criterion 2.1.2.2.

2.5.4.2 No failures in the performance of the IVAC® Model 4000AEE were noted before, during, or after the altitude test. Criterion met.

2.5.4.3 The posttest performance check met criterion 2.1.2.2.

2.6 VIBRATION TEST [IAW MIL-STD-810D, METHOD 514.3]

2.6.1 Objective

To determine the ability of the IVAC® Model 4000AEE to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

2.6.2 Criterion

The IVAC® Model 4000AEE will remain operational and be able to display consistent and accurate measurements while exposed to vibrational stresses.

2.6.3 Test procedure

2.6.3.1 A pretest performance check was conducted to ensure proper operation of the IVAC® Model 4000AEE.

2.6.3.2 The vibration test was performed using an Unholtz-Dickey model TA115-40/CSTA vibration test system*. It is a single-axis system with an electromagnetic driver unit. The test consisted of sinusoidal vibrations superimposed on random vibrations over a frequency range of 500 Hz, as shown below. These vibrations are derived from measurements taken on the floor under the copilot's seat in a UH-1 helicopter traveling at 120 knots. The reference spectrum breakpoints are from MIL-STD-810D, Method 514.3;

reference spectrum levels are based on field measurements with a conservatism factor of 1.5. Independent tests were conducted in the X, Y, and Z axes.

Z-axis
duration: 60 minutes
broadband intensity: 0.4506 G_{rms}
random vibration: initial slope : 99.00 dB/Hz
5 Hz level: 0.00006210 $G_{sqr/Hz}$
100 Hz level: 0.0006210 $G_{sqr/Hz}$
300 Hz level: 0.0006210 $G_{sqr/Hz}$
500 Hz level: 0.00006210 $G_{sqr/Hz}$
final slope: -99.00 dB/oct
sinusoidal vibration: .5450 G_{pk} at 11.25 Hz
.1690 G_{pk} at 22.50 Hz
.1200 G_{pk} at 33.75 Hz
.0310 G_{pk} at 45.00 Hz
.0530 G_{pk} at 56.25 Hz

X and Y axes
duration: 60 minutes each
broadband intensity: 0.3099 G_{rms}
random vibration: initial slope: 99.00 dB/oct
5 Hz level: 0.00002920 $G_{sqr/Hz}$
100 Hz level: 0.0002920 $G_{sqr/Hz}$
300 Hz level: 0.0002920 $G_{sqr/Hz}$
500 Hz level: 0.00002920 $G_{sqr/Hz}$
final slope: -99.00 dB/oct
sinusoidal vibration: .3200 G_{pk} at 11.25 Hz
.0670 G_{pk} at 22.50 Hz
.0950 G_{pk} at 33.75 Hz
.0350 G_{pk} at 45.00 Hz
.0770 G_{pk} at 56.25 Hz

The IVAC® Model 4000AEE was strapped to the vibration table fixture, and its performance was evaluated before, during, and after exposure to vibration.

2.6.3.3 A posttest performance check was conducted to ensure proper operation of the IVAC® Model 4000AEE.

2.6.4 Test findings

2.6.4.1 The pretest performance check met criterion 2.1.2.2.

2.6.4.2 No failures in the performance of the IVAC® Model 4000AEE occurred before, during, or after exposure to vibration. Criterion met.

2.6.4.3 The posttest performance check met criterion 2.1.2.2.

2.7 HIGH TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 501.2]

2.7.1 Objective

To determine the ability of the IVAC® Model 4000AEE to be stored and operated in a high-temperature environment.

2.7.2 Criteria

2.7.2.1 The IVAC® Model 4000AEE will display consistent and accurate measurements during the high-temperature operation check.

2.7.2.2 The IVAC® Model 4000AEE will display consistent and accurate measurements after the high-temperature storage cycle.

2.7.3 Test procedure

2.7.3.1 A pretest performance check was conducted to ensure proper operation of the IVAC® Model 4000AEE.

2.7.3.2 The high-temperature test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 501.2. For the high-temperature operation test, the IVAC® Model 4000AEE was turned on in the standby mode and placed on the floor of the environmental chamber. The chamber temperature was raised to 49°C and the humidity was stabilized at a maximum of 20 percent RH within 15 minutes. The environmental control system is capable of regulating temperature within ± 2°C and humidity within ± 5 percent RH. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions during performance checks. After the operational test, the IVAC® Model 4000AEE was allowed to return to ambient conditions over a 30-minute period.

2.7.3.3 A posttest performance check was conducted to ensure proper operation of the IVAC® Model 4000AEE.

2.7.3.4 The IVAC® Model 4000AEE was stored (not operated) at temperatures of 63°C for 1 hour, 71°C for 4 hours, then again at 63°C for 1 hour. The chamber and IVAC® Model 4000AEE then were returned to ambient conditions over a 30-minute period.

2.7.3.5 A poststorage performance check was conducted to ensure proper performance of the IVAC® Model 4000AEE.

2.7.4 Test findings

2.7.4.1 The pretest performance check met criterion 2.1.2.2.

2.7.4.2 No operational failures occurred during the high-temperature test. Criterion met.

2.7.4.3 The posttest performance check met criterion 2.1.2.2.

2.7.4.4 The IVAC® Model 4000AEE functioned properly after the high-temperature storage test. Criterion met.

2.8 LOW TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 502.2]

2.8.1 Objective

To determine the ability of the IVAC® Model 4000AEE to be stored and operated in a low-temperature environment.

2.8.2 Criteria

2.8.2.1 The IVAC® Model 4000AEE will display consistent and accurate measurements during the low-temperature operation check.

2.8.2.2 The IVAC® Model 4000AEE will display consistent and accurate measurements after the low-temperature storage cycle.

2.8.3 Test procedure

2.8.3.1 A pretest performance check was conducted to ensure proper operation of the IVAC® Model 4000AEE.

2.8.3.2 The IVAC® Model 4000AEE was placed on the floor of the environmental chamber and the temperature was lowered to 0°C within 25 minutes. The environmental control system is capable of regulating temperature within 2°C. Humidity cannot be controlled in the chamber at freezing temperatures. The temperature was held constant for 2 hours. Every 30 minutes, the chamber door was opened briefly to minimize the change in chamber conditions and a performance check was conducted. The chamber temperature then was raised to ambient temperature within a 30-minute period.

2.8.3.3 A posttest performance check was conducted to ensure proper operation of the IVAC® Model 4000AEE.

2.8.3.4 The IVAC® Model 4000AEE was "stored" in a nonoperational mode. The IVAC® Model 4000AEE was placed on the floor of the environmental test chamber and the temperature was lowered to -46°C for 6 hours. The chamber then was raised to ambient temperature over a 30-minute period.

2.8.3.5 A poststorage performance check was conducted to ensure proper operation of the IVAC® Model 4000AEE.

2.8.4 Test findings

2.8.4.1 The pretest performance check met criterion 2.1.2.2.

2.8.4.2 No operational failures occurred during the low-temperature test. Criterion met.

2.8.4.3 The posttest performance check met criterion 2.1.2.2.

2.8.4.4 The IVAC® Model 4000AEE functioned properly after the low-temperature storage test. Criterion met.

2.9 HUMIDITY TEST [IAW MIL-STD-810D, METHOD 507.2]

2.9.1 Objective

To determine the ability of the IVAC® Model 4000AEE to operate satisfactorily for short periods of time during exposure to highly humid conditions.

2.9.2 Criterion

The IVAC® Model 4000AEE will display consistent and accurate measurements while exposed to a high humidity environment.

2.9.3 Test procedure

2.9.3.1 A pretest performance check was conducted to ensure the proper operation of the IVAC® Model 4000AEE.

2.9.3.2 The humidity test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 507.2. For the humidity test, the IVAC® Model 4000AEE was placed ready for operation on the floor of the environmental chamber. The chamber temperature was raised to a temperature of 30°C and a relative humidity of 95 percent within 25 minutes. Temperature and relative humidity were maintained for 4 hours. The environmental control system is capable of regulating temperature within ± 2°C and humidity within ± 5 percent RH. At 45-minute intervals the performance of the BP monitor was checked. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and the IVAC® Model 4000AEE were returned to ambient conditions before the posttest performance validation check was conducted.

2.9.3.3 A posttest performance check was conducted to ensure the proper operation of the IVAC® Model 4000AEE.

2.9.4 Test findings

2.9.4.1 The pretest performance check met criterion 2.1.2.2.

2.9.4.2 No failures were noted in the IVAC® Model 4000AEE performance checks conducted during the exposure to the high humidity environment. Criterion met.

2.9.4.3 The posttest performance check met criterion 2.1.2.2.

2.10 ELECTROMAGNETIC CHARACTERISTICS TEST [IAW MIL-STD-461A, Notice 4, and MIL-STD-462, Notice 3]

2.10.1 Objectives

2.10.1.1 To assess the maximum levels of radiated electromagnetic emissions produced by the IVAC® Model 4000AEE in the 14 kHz to 12.4 GHz frequency range.

2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the IVAC® Model 4000AEE within the 10 kHz to 10 GHz electric field.

2.10.1.3 To assess the maximum levels of conducted electromagnetic emissions produced by the IVAC® Model 4000AEE in the 10 kHz to 50 MHz frequency ranges.

2.10.1.4 To assess the tolerances of conducted electromagnetic susceptibility of the IVAC® Model 4000AEE within the range of 50 kHz to 400 MHz and power spikes.

2.10.2 Criteria

2.10.2.1 The IVAC® Model 4000AEE will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.

2.10.2.2 The IVAC® Model 4000AEE will not malfunction when it is subjected to radiated emissions as specified in MIL-STD-461A, Notice 4, paragraph 6.20.

2.10.2.3 The IVAC® Model 4000AEE shall not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraphs 6.1 and 6.2.

2.10.2.4 The IVAC® Model 4000AEE shall not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.

2.10.3 Test procedure

2.10.3.1 The radiated emissions test was performed according to MIL-STD-462, Notice 3, Method RE02. The IVAC® Model 4000AEE was positioned on a wooden test stand inside the EMI chamber, 1 meter away from the receiving antennas. The antennas were mounted for both vertical and horizontal polarities and connected to EMI receivers. The IVAC® Model 4000AEE was connected through an extended tube to a cuff outside the chamber. The cuff was placed around a test engineer's arm while the IVAC® Model 4000AEE took BP measurements at 2.5-minute intervals. While the IVAC® Model 4000AEE was operating, the frequency spectrum (14 kHz to 12.4 GHz) was scanned for emissions. The IVAC® Model 4000AEE was operated with both ac and battery power.

2.10.3.2 The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RS03. The IVAC® Model 4000AEE was positioned on a wooden test stand inside the EMI chamber 1 meter away from the transmitting antennas. The antennas were mounted for both vertical and horizontal polarities and connected to radio frequency (RF) transmitters. The IVAC® Model 4000AEE was operating in the monitor temperature mode. The BP portion of the unit was in standby mode. While the IVAC® Model 4000AEE was operating, it was monitored for faulty operation during exposures to fields of 1 V/m from 10 kHz to 2 MHz, and 5 V/m from 2 to 30 MHz, 10 V/m from 30 MHz to 2 GHz, and 5V/m from 2 to 10 GHz. The IVAC® Model 4000AEE was operated with ac power only.

2.10.3.3 The conducted emissions tests were performed according to MIL-STD-462, Notice 3, Methods CE02 and CE04. The IVAC® Model 4000AEEE was placed on a grounded, copper covered workbench. The top of the workbench was 1 meter from floor level, 1.37 meters long and 0.81 meters wide. Power was supplied via a pair of line impedance stabilization networks (LISN) and a test jig. The test jig is a wooden tray with two power receptacles and two slots to hold current probes in place around power supply conductors. While the IMED 927 was operating, the frequency range (10 kHz to 50 MHz) was scanned for emissions conducted in the power cable from the IVAC® Model 4000AEE.

2.10.3.4 The conducted susceptibility spike test was performed according to MIL-STD-462, Notice 3, Method CS06, on a chemical resistant counter top. Power was supplied via a customized metal connection box. The connection box has two power receptacles and four banana jacks on its front panel. Connections to the individual power lines are made in series through the banana jacks. Transient spikes of 100 volts, 10 microseconds were generated with a Solar Electronics model 8282-1 transient pulse generator* and induced onto the power leads at the connection box banana jacks. The spikes were monitored with a Tektronix 2235 oscilloscope* connected to a power receptacle on the connection box. The IVAC® Model 4000AEE was plugged into the other receptacle on

the connection box and placed in operation. It was observed for correct operation and visual displays while it was subjected to the power line spikes.

2.10.3.5 The conducted susceptibility test was performed according to MIL-STD-462, Notice 3, Method CS02. The IVAC® Model 4000AEE was placed on a grounded, copper covered workbench. Radio frequency interference was induced on the power leads and measured at the IMED 927 power cable. The frequency of the interference was incremented over the 50 kHz to 400 MHz range while the IVAC® Model 4000AEE was operated. It was observed for correct operation and visual displays while it was subjected to the radio interference on the power leads. Each frequency was held for 15 seconds.

2.10.4 Test findings

2.10.4.1 During the radiated emissions test, emissions which exceeded specification limits of MIL-STD-461A, Notice 4, were detected. These included:

Power	Frequency range	Emission exceeding standard
ac:	0.024 - 242 MHz	0.2 - 46.8 dB (NB)
	5.500 - 30 MHz	0.8 - 12.3 dB (BB)
ac:	0.557 - 229.125 MHz	0.1 - 45.8 dB (NB)
	20.538 - 45 MHz	0.8 - 20.3 dB (BB)

Criterion partially met.

2.10.4.2 The IVAC® Model 4000AEE was found to be susceptible to radio frequency interference in the testing range and magnitude.

Frequency range	Maximum field strength without susceptibility
33.4 - 200 MHz	0.89 - 6.68 V/m
200.0 - 332 MHz	0.79 - 5.31 V/m
556.0 - 592 MHz	5.01 - 7.50 V/m

Criterion partially met.

2.10.4.3 Narrowband emissions of 0.7 to 7.5 dB over specification were detected from 19.03 to 41.898 MHz. Criterion partially met.

2.10.4.4 The test signals were not detectable on the power lines due to conducted emissions from the IVAC® Model 4000AEE. The IVAC® Model 4000AEE was not susceptible to test spikes during the conducted susceptibility tests. Criterion partially met.

2.11 IN-FLIGHT HUMAN FACTORS EVALUATION

2.11.1 Objective

To assess the physical and/or functional compatibility of the IVAC® Model 4000AEE while in use on board the aircraft.

2.11.2 Criterion

The flight surgeon will be able to operate the IVAC® Model 4000AEE without physical or functional restrictions aboard the aircraft. Major areas of concern include: Proper operation, visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.11.3 Test procedure

2.11.3.1 A human factors evaluation was performed IAW MIL-STD-1472D, AAMI human factors engineering guidelines, and UL-544 to ensure the compatibility of the IVAC® Model 4000AEE and the in-flight environment. The flight surgeon conducted the test wearing a flight suit, flight gloves, and an SPH-4 flight helmet. An evaluation of the compatibility with the nuclear, biological, and chemical (NBC) protective equipment was not conducted. Due to restrictions of the AWR, testing was conducted during daylight hours only.

2.11.3.2 The IVAC® Model 4000AEE was placed on the floor of the aircraft next to the bottom pan of the litter carousel which was configured for four patients. The litter carousel was flown in the "load" position (perpendicular to the long axis of the helicopter). The IVAC® Model 4000AEE was tested with the cuff placed on the right arm of a simulated patient lying in the bottom pan of the litter carousel. The IVAC® Model 4000AEE was tested using both ac and battery power in all flight scenarios required by the In-Flight Test Operations Procedures (ITOP) (refer to section 3.2).

2.11.4 Test findings

During the in-flight human factors evaluation, the IVAC® Model 4000AEE was found to be satisfactory in all but two of the categories of the evaluation criteria. The first deficiency was the lack of brightness control on the LED display noted in the laboratory evaluation (paragraph 1.5.1.3). In addition, audio alarms were not audible above the ambient noise in the aircraft. Ambient noise levels prevented reception and interpretation of Korotkoff sounds by the IVAC® Model 4000AEE. Background noise was frequently interpreted as a Korotkoff sound and cuff pressures increased to their maximum (>250 mmHg). This resulted in

high cuff pressures, delays in the machine cycle, and erroneous heart rate and BP measurements. Errors were noted in 50 percent of the machine cycles during ground operation, 30 percent during hover, and 90 percent during cruise flight. These errors could not be prevented by moving the cuff to the other arm, muffling the microphone, or changing patient position. The temperature probe worked properly in all phases of flight.

Criterion partially met.

2.12 IN-FLIGHT EMI/EMC CHARACTERISTICS

2.12.1 Objective

To assess the EMI/EMC characteristics of the IVAC® Model 4000AEE with the host aircraft and its installed systems.

2.12.2 Criteria

2.12.2.1 The IVAC® Model 4000AEE will not radiate EMI to disrupt or interfere with other equipment or systems aboard the aircraft.

2.12.2.2 The aircraft will not radiate EMI to disrupt or interfere with the IVAC® Model 4000AEE's operation.

2.12.3 Test procedure

A qualitative EMI/EMC assessment was performed with both the IVAC® Model 4000AEE and the aircraft operating as source and victim. The IVAC® Model 4000AEE and applicable aircraft instruments and systems were monitored for unusual operation, readings, surges, or power anomalies for each checklist item (see pages 3-5 through 3-8).

2.12.4 Test findings

2.12.4.1 There were no adverse instances of EMI/EMC noted with the IVAC® Model 4000AEE acting as either the source or victim. Criterion met.

2.12.4.2 There were no adverse instances of EMI/EMC noted with the aircraft acting as either the source or victim. Criterion met.

Section 3. Supporting documentation

3.1 DETAILED TEST INFORMATION

3.1.1 General information

3.1.1.1 IVAC® Model 4000AEE testing is not considered a major action significantly affecting the quality of the human environment and, therefore, qualifies for categorical exclusion A-28, appendix A, AR 200-1.

3.1.1.2 A safety pilot will be designated for each flight. Flight operations will be conducted IAW the aircraft operator's manual, appropriate aircrew training manuals, and test item technical data.

3.1.2 Material description

3.1.2.1 The IVAC® Model 4000AEE Vital Check Monitor is a portable device designed to measure a patient's BP and temperature. The front panel contains LED displays that show the patient's systolic pressure, diastolic pressure, MAP, pulse and temperature. The BP measurements may be initiated manually or automatically at timed intervals. A control knob on the front panel allows the user to select cuff pressures of 100, 125, 150, or 200 mmHg. A second control knob allows the user to select automatic BP measurements at 1-, 2.5-, 5-, 15-, or 30-minute intervals. The unit can recall up to 20 BP readings. The monitor will reinflate the cuff when it detects artifact, low signal intensity, or an unusually high BP reading. The unit provides a visual display of the Korotkoff sounds and is equipped with a stethoscope attachment to monitor the sounds. The visual display of the Korotkoff sounds is presented on the front panel under the pulse reading. The on/off and start/reset buttons are located under the control knobs on the front panel. A control switch on the rear panel selects whether temperature readings are displayed in Fahrenheit or Celsius. Audible beeps indicate when a new BP or predictive temperature has been reached.

3.1.2.2 Method of operation: The IVAC® Model 4000AEE Vital Check Monitor is a microprocessor based unit which displays systolic pressure, diastolic pressure, MAP, pulse, and temperature. The BP is found using two methods: An auscultation method, and an oscillometry method. The unit can read BP up to 275 mmHg systolic pressure and down to 20 mmHg diastolic pressure. An erratic pulse is represented by flashing decimal points under the reading. There are two modes of measuring temperature, predictive and monitor. The predictive mode ranges from 32.2°C to 42.1°C (90.0°F to 107.9°F) and the monitor mode ranges form 31.1°C to 42.1°C (88.0°F to 107.9°F). Error messages are

displayed on the front panel and, in the event of an internal malfunction, the unit will display "FIX ME" followed by a character to identify the malfunction.

3.1.2.3 Dimensions: 8.83 x 5.63 x 11.63 in. (21.27 x 14.29 x 29.53 cm).

3.1.2.4 Weight: 15.8 lb (7.2 kg).

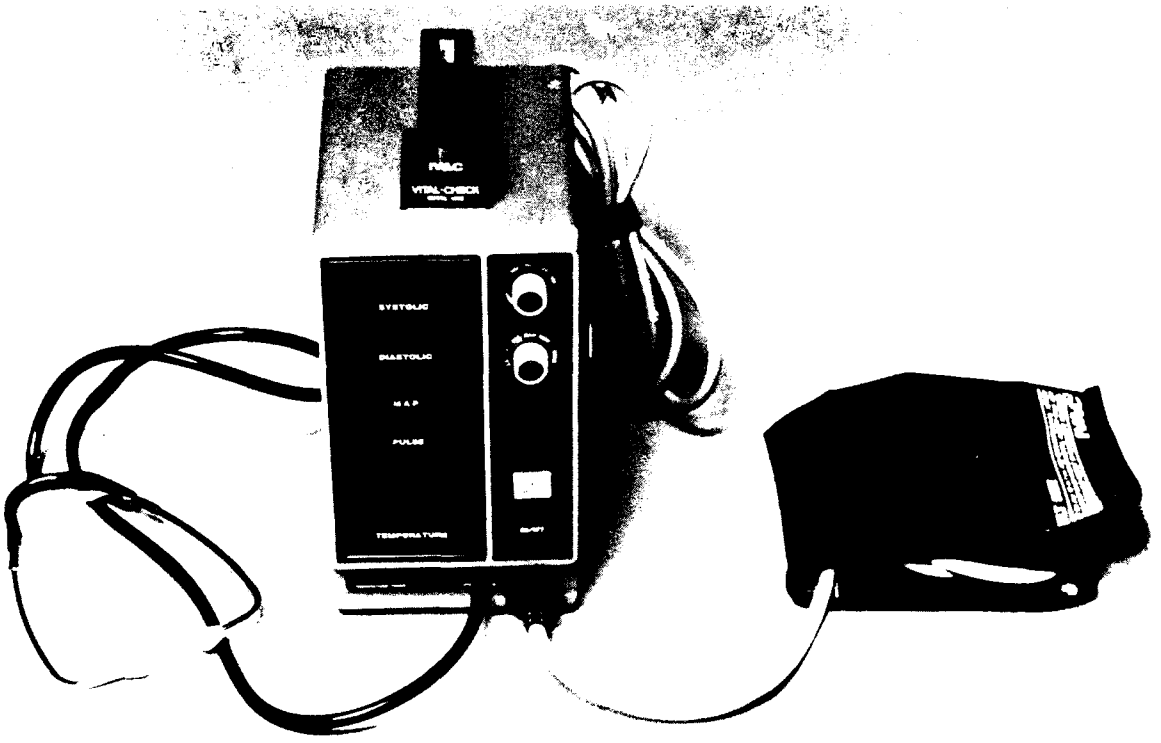
3.1.2.5 Standard accessories: Stethoscope with luer connector, IVAC® standard probes and disposable probes, pediatric cuff, adult cuff, and operating instructions.

3.1.2.6 Power requirements: 95 to 135 Vac, 50 or 60 Hz, 0.7 amp, 3-wire grounded system. Internal battery is a rechargeable lead-acid type which provides 2.5 hours of rated operation or approximately 150 BP measurements. Charge time for a completely discharged battery to full charge is 12 to 16 hours. Power cord is PECO, 18-3, type SJT, PE CO, of approximately 116 inches in length.

3.1.2.7 Environmental considerations: Atmospheric pressure, less than 11,000 feet; operating temperature, 5 to 45 degrees C; storage temperature, -30 to 65 degrees C; relative humidity, 0 to 95 percent.

3.2 TEST DATA

3.2.1 Photographic description



3.2.2 Aircraft equipment list

Item No.	Nomenclature
1	Receiver radio -- R-1496A/ARN-89 (automatic direction finder)
2	Displacement gyro -- CN-1314/A
3	Gyro directional -- CN-998/ASN-43
4	Signal data converter -- CV-3338/ASN-128
5	Receiver -- R-2139/ARN-123 (VOR/LOC/MB/GS)
6	Command instrument system processor -- 70600-01038-101
7	SAS amplifier -- 70901-02908-104 (flight control stability augmentation system)
8	Rate gyro -- TRU-2A/A
9	Amplifier, impedance -- AM-4859A/ARN-89
10	Cargo hook -- FE-7590-145
11	Receiver, radar -- RT-1193/ASN-128 (doppler navigation receiver)
12	Barometric altimeter -- AAU-31/A-1
13	Barometric altimeter -- AAU-32A
14	Receiver/transmitter -- RT-1300/ARC-186 (VHF-AM and/or FM radio)
15	UHF-AM radio set -- RT-1518/ARC-164
16	Interphone control -- C6533/ARC (aircraft intercom control)
17	Receiver/transmitter -- RT-1115D/APN-209 (radar altimeter)
18	Indicator altimeter -- ID-1917C/APN-209 (radar altimeter)
19	Control radio set -- C-7392A/ARN-89 (automatic direction finder)
20	Comparator signal data -- CM-482/ARC-186 (comparator for ARC-186)
21	Receiver/transmitter -- RT-1296A/APX-100 (transponder with IFF)
22	Computer display unit -- CP-1252/ASN-128 (doppler navigation system)
23	Compass set controller -- C-8021E/ASN75
24	Magnetic compass - standby -- MS-17983-4

3.2.3 In-flight test data card

DATA CARD FORMAT

GUIDELINE FOR DATA COLLECTION

IN-FLIGHT SUITABILITY TEST OF MEDICAL ITEMS

1. Installation/removal.	Suitable Yes	Suitable No	Comments
a. Weight and balance (DD Form 365-4, Clearance Form F).	X		
b. Space/area allocation.			
(1) Operational requirements.	X		
(2) Storage requirements.	X		
c. Interface connections (safe, positive, secure).	X		
d. Installation/removal (expedient/easily achieved).	X		
e. Mounting/final configuration (functional/stable).	X		

2. Operations and performance.	Suitable Yes	Suitable No	Comments
a. Manufacturer's operating instruction.	X		
b. Medical item operation before aircraft run-up.	X		
c. System interface during aircraft engine run-up and medical item operation (EMI switchology checklist).	X		
(1) Aircraft voltage output.	X		

	Suitable Yes	Suitable No	Comments
(2) Flight control function (UH-60).	X		
(3) Stabilator function (UH-60).	X		
(4) Radio communication vs medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		
(5) Navigation equipment vs medical item operation.			
(a) Transponder	X		
(b) ADF	X		
(c) VOR	X		
(d) Doppler	X		
(6) Radar altimeter operation vs medical item operation.	X		
d. System interface during aircraft hover and medical item operation (EMI switchology checklist).			
(1) Voltage output.	n/a		
(2) Radio communication vs medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		

	Suitable Yes	No	Comments
(3) Navigation equipment operation vs medical item operation.			
(a) Transponder	X		
(b) ADF	X		
(c) VOR	X		
(d) Doppler	X		
e. Flight mission profile vs medical item operation (EMI switchology checklist).			
(1) Straight and level (1000 ft MSL for 20 minutes).			
(a) Compatibility of flight mode and medical item operation.	X		
(b) Radio communication vs medical item operation.			
a. FM	X		
b. UHF	X		
c. VHF	X		
(2) NOE (20 minutes). compatibility of flight mode and medical item operation.	X		
(3) FM homing (10 minutes).	X		
(4) Doppler navigation vs medical item operation.			
(a) Initialize function.	X		
(b) Fix function.	X		
(c) Update function.	X		

	Suitable Yes	Suitable No	Comments
(5) VOR navigation 7000 ft MSL for 20 minutes) vs medical item operation.	X		
(6) ILS approach vs medical item operation.	X		
f. Medical item operation after engine shutdown (external power source).	X		
g. Restrictions to the medical item's use (i.e., electrical connectors).	X		
h. Deviations from the laboratory test results.			
(1) Electrical/ electronic.	None		
(2) Mechanical environment.	See comment 3b.		
(3) Human factors (user interface, controls, markings, lighting, egress).	None		
(4) Safety.	None		

3. Deviations from the in-flight test protocol.

a. The VOR navigation portion of the in-flight test conducted at 2000 feet MSL due to air traffic control clearance.

b. Ambient noise levels in all phases of flight prevented proper reception and interpretation of Korotkoff sounds. Countermeasures included changing the cuff to the other arm, changing arm position, and muffling the microphone area. These countermeasures did not improve reception of these sounds in operational testing.

3.2.4 EMI switchology checklist

EMI SWITCHOLOGY CHECKLIST UH-60 AIRCRAFT

IN-FLIGHT SUITABILITY OF MEDICAL ITEMS

ENG INSTRUMENTS/CDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Fuel quantity	X			
Fuel indicator test	X			
XMSN oil temperature	X			
XMSN oil pressure	X			
#1 engine oil temperature	X			
#2 engine oil temperature	X			
#1 engine oil pressure	X			
#2 engine oil pressure	X			
#1 TGT	X			
#2 TGT	X			
#1 Ng speed	X			
#2 Ng speed	X			
CDU digits on/off	X			
CDU instruments dim	X			

ENG INSTRUMENTS/PLT PDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 engine RPM	X			
#2 engine RPM	X			
Rotor RPM	X			
#1 torque	X			
#2 torque	X			

ENG INSTRUMENTS/COPLT PDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 engine RPM	X			
#2 engine RPM	X			
Rotor RPM	X			
#1 torque	X			
#2 torque	X			

ENG CONTROLS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 overspeed	X			
#2 overspeed	X			
RPM switch	X			
#1 engine anti-ice	X			
#2 engine anti-ice	X			
#1 inlet anti-ice	X			
#2 inlet anti-ice	X			

RADIO EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
ICS, C-6533 ARC	X			
VHF-FM, ARC-186/115	X			
VHF-AM, ARC-186/115	X			
UHF-AM, ARC-164(V)	X			
Crypto, KY-28	Not installed			
Radio retransmissions PLN	Not installed			
Transponder, APX-100(V)	X			
KIT-1A/TSEC IFF computer	Not keyed with code			

MISSION EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
RWR, APR-39(V)	Not installed			
IR CM, ALQ-144	Not installed			
Chaff dispenser, M-130	Not installed			
Cargo hook system	X			

HYDRAULIC CONTROL SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Backup hydraulic pump	X			
Servo off 1st stage/PLT	X			
Servo off 2nd stage/PLT	X			
Servo off 1st stage/COPLT	X			
Servo off 2nd stage/COPLT	X			
Hydraulic leak test	X			
Tail servo	X			
Boost servos	X			

FUEL SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Fuel pump switch	X			
Fuel boost pump #1	X			
Fuel boost pump #2	X			
Fuel cont panel ESSS	Not installed			

WARNING SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Low rotor RPM	X			
Master caution	X			
Caution advisory	X			
Fire warning	X			
AFCS	X			
Stabilator	X			
#1 engine out	X			
#2 engine out	X			

NAVIGATION INSTRUMENTS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
ADF	X			
Magnetic compass	X			
CONUS NAV, ARN-123	X			
Doppler, ASN-128	X			
Gyro mag compass (PLT)	X			
Gyro mag compass (COPLT)	X			
Compass cont panel, ASN-75	X			
HSI	X			

FLIGHT INSTRUMENTS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Radar altimeter	X			
Stabilator pos indicator	X			
VSI	X			
CIS mode select	X			
SAS 1	X			
SAS 2	X			
FPS	X			
Trim	X			
Go-around enable	X			
Cyclic trim release	X			
Cyclic stick trim	X			
ALR encoder	X			

FLIGHT INSTRUMENTS (CONT)	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
HSI/VSI mode select (PLT)				
DPLR	X			
VOR/ILS	X			
BACK CRS	X			
FM HOME	X			
TURN RATE	X			
CRS HDG	X			
VERT GYRO	X			
BRG 2	X			
HSI/VSI Mode Select (COPLT)				
DPLR	X			
VOR/ILS	X			
BACK CRS	X			
FM HOME	X			
TURN RATE	X			
CRS HDG	X			
VERT GYRO	X			
BRG 2	X			

MISCELLANEOUS EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Blade deice	Not tested			Ambient temperature was out of test limits.
Windshield anti-ice	X			
Pitot heat	X			
Vent blower	X			
Windshield wiper	X			
Heater	X			
APU	X			
Generator #1	X			
Generator #2	X			
Generator APU	X			
Air source heat start	X			
Tail wheel lock	X			
Gyro erect	X			

LIGHTING	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Cockpit utility	X			
Cockpit flood	X			
Cabin dome	X			
Search light	X			
Search light control	X			
Landing light	X			
Flt instr lights (PLT)	X			
Flt instr lights (COPLT)	X			
Nonflight instr lights	X			
Console lights, upper	X			
Console lights, lower	X			
Position lights	X			
Formation lights	X			
Anticollision lights	X			
NVG lighting	X			

3.2.5 Battery life evaluation

Battery Life Evaluation
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Manufacturer battery life specification: 2.5 hours or 150 BP measurements.

Specified battery recharge time: 12 to 16 hours.

Specified mode of operation under battery power: 2.5 minute cycle mode, in which automatic BP measurements are taken at 2.5 minute intervals.

Overall performance: Pass

Measurements: The unit averaged 7 hours and 13 minutes of operation in the 2.5 minute mode.

Comments: None

3.2.6 Electrical safety test

Electrical Safety Test
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Date of test: 5 Apr 89

Measurements:

Grounding conductor resistance (milliohms): 69.3

Leakage current - Case to ground (microamperes):

unit off, grounded, normal polarity	1.5
unit off, ungrounded, normal polarity	11.3
unit off, ungrounded, reverse polarity	11.5
unit on, grounded, normal polarity	11.5
unit on, ungrounded, normal polarity	11.3
unit on, ungrounded, reverse polarity	11.5

MAXIMUM LIMITS:

ground resistance (milliohms):	150
current (microamperes)	
current (grounded, type A unit):	10
current (ungrounded, type A unit):	100
current (grounded, type B unit):	50
current (ungrounded, type B unit):	500

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.7 Human factors evaluation

Human Factors Evaluation
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Date of test: 5 Apr 89

Item configuration during test: Item prepared for operation, sitting on a counter top.

Checklist for HFE

RESULTS

VISUAL DISPLAYS: Unsatisfactory

display type, format, content
location of displays
indicator lights
scalar displays
color coding
legends and labels
cathode ray tubes
counters
flags, go-no-go, center-null indicators

Comments: Scalar displays, color coding, counters, and cathode ray tubes (CRT) are not applicable. The LED's are red in color and have no brightness controls. Controls are not illuminated for low light conditions.

CONTROLS: Satisfactory

location
characteristics of controls
labeling
control - display relationships

Comments:

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: 2 minutes required to prepare for operation.

MAINTAINABILITY: Satisfactory

component location
component characteristics
rests and stands
covers, cases, access doors
handles
lubrication
component mounting
cord storage provisions
external accessibility
internal accessibility
list special tools required
list realistic inspection requirements
list realistic inspection intervals

Comments: A standard cross-point screwdriver is needed to access the battery and computer interface module. A self-test is initiated at each power-on. A 6-month interval for operational, electrical, damage and wear inspections and calibration are listed in the operator's manual.

CONDUCTORS: Satisfactory

binding and securing
length
protection
routing
conductor coding
fabrication
connectors

Comments: None

FASTENERS: Satisfactory

access through inspection panel covers
enclosure fasteners
device mounting bolts and fasteners

Comments: The enclosure is held in place with cross-point screws.

TEST POINTS: Satisfactory

general
location and mounting
test point labeling and coding

Comments: A display test pushbutton is mounted on the rear panel.

TEST EQUIPMENT: Satisfactory

general
equipment self-test
indicators (list in comments)
controls
positive indication of proper operation

Comments: An internal self-test outputs codes for normal status and for failures. A connector for external pressure calibration is located on the rear panel.

FUSES AND CIRCUIT BREAKERS: Satisfactory

external accessibility
easy replacement or reset by operator

Comments: A pushbutton reset circuit breaker is located on the rear panel.

LABELS and CODING: Satisfactory

placed above controls and displays
near or on the items they identify
not obscured by other equipment components
describe the function of the items they identify
readable from normal operating distance
conspicuous placards adjacent to hazardous items

Comments: None

SAFETY: Satisfactory

manual
materials
fire and explosive protection
operator protection from mechanical hazards
patient protection from mechanical hazards
electrical safety (operator and patient)

Comments: A placard warns against operation in the presence of flammable anesthetics. The pump shuts down and releases cuff pressure when an overpressure state occurs.

3.2.8 Altitude test

Altitude Test
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Date of test: 10 Apr 89

Item configuration during test: Item turned on in the standby mode, operating on dc (battery) power, sitting on chamber floor.

Performance test criteria: Consistent and accurate displays and measurements

Ambient conditions outside chamber:

Temperature	59°F
Humidity	62% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None (battery)
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	ac

IN-TEST DATA

Time of test start: 0905

POSTTEST DATA

Posttest performance check (complete check of item and accessories):

Time of test end: 1035

Item functional (based on performance test criteria): Yes

Deviation from pretest : None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.9 Vibration test

Vibration Test
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Date of test: 10 Apr 89

Item configuration during test: Item strapped down on vibration table fixture; ac and dc operation.

Performance test criteria: Consistent and accurate measurements and displays.

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	None

Ambient conditions

Temperature	68°F
Humidity	59% RH
Barometric pressure	1 atm

IN-TEST DATA

Data and performance checks during test:

Time at first check:
X: 1430 (4-10-89) Y: 1535 (4-10-89) Z: 0755 (4-11-89)

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Time at second check:
X: 1525 Y: 1630 Z: 0850

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

POSTTEST DATA

Time at test end:

Posttest performance check (complete check of item and accessories):

Item functional (based on performance test criteria): Yes

Item intact: Yes

Deviation from pretest: None

Comments on item setup or checks:
The test engineer's arm was used to check the accuracy of the unit and an Extech thermometer was used to check the accuracy of the temperature probe. Times are on different days.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.10 High temperature test

High Temperature Test
(Equipment Operating)
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Date of test: 10 May 89

Item configuration during test: Unit was sitting on chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	61% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check :
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

IN-TEST DATA

Time of test start: 0815

Performance checks during test:

First check:

Time:	0845
Temperature:	49°C
Humidity:	15% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes, all ok
Deviation from pretest:	None

Second check:

Time:	0915
Temperature:	49°C
Humidity:	15% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes, all ok
Deviation from pretest:	None

Third check:

Time:	0945
Temperature:	49°C
Humidity:	15% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes, all ok
Deviation from pretest:	None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end:	1040
Item functional (based on performance test criteria):	Yes, all ok
Deviation from pretest:	None

Comments on item setup or checks:
The test engineer's arm was used to test the unit's accuracy during performance checks.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.11 High temperature storage test

High Temperature Test
(Equipment in Storage)
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Date of test: 11 May 89

Item configuration during test: Sitting on chamber floor, in storage, not operating.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	50% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	all
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

Time of test start: 1115

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1445
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks:
The unit was allowed to cool overnight, before the posttest performance check was completed.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.12 Low temperature test

Low Temperature Test
(Equipment Operating)
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Date of test: 10 May 89

Item configuration during test: Sitting on chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	not available
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Pass

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

Time of test start: 1100

Performance checks during test:

First check:

Time:	1130
Temperature:	0°C
Humidity:	n/a
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Second check:

Time:	1200
Temperature:	0°C
Humidity:	n/a
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Third check:

Time:	1230
Temperature:	0°C
Humidity:	n/a
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end:	1315
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Comments on item setup or checks:
The test engineer's arm was used to test the accuracy of the unit.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.13 Low temperature storage test

Low Temperature Test
(Equipment in Storage)
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Date of test: 12 May 89

Item configuration during test: ac power cord and cuff tube coiled and laying on top of the unit. The unit is in storage, not operating.

Performance test criteria: Consistent and accurate displays and measurements

Ambient conditions outside chamber:

Temperature	23°C
Humidity	50% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

Time of test start: 0800
Midtest time: 1130
Midtest temperature: -46°C

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1500
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: The unit was allowed to return to ambient conditions overnight before final performance check.

3.2.14 Humidity test

Humidity Test
Report Form

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: None

Options installed: None

Date of test: 15 May 89

Item configuration during test: The unit was sitting on the chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	62% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

IN-TEST DATA

Time of test start: 0845

Performance checks during test:

First check:

Time:	0930
Temperature:	29.5°C
Humidity:	95% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Second check:

Time:	1015
Temperature:	29.5°C
Humidity:	95% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Third check:

Time:	1100
Temperature:	29.5°C
Humidity:	95% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Fourth check:

Time:	1145
Temperature:	29.5°C
Humidity:	95% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Fifth check:

Time:	1230
Temperature:	29.5°C
Humidity:	95% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 1400
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.15 Electromagnetic characteristics test

****

Electromagnetic Characteristics Testing
Evaluation of Performance
****

T & E Item Number: 14 Date: 12 Apr 89

Nomenclature: Vital check monitor
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 4000AEE
Serial number: 010013
Military item number: n/a

****

Conducted Emissions Tests

CE01 Testing configuration(s): n/a
Performance (pass/fail): n/a

Comments: n/a

CE02 Testing configuration(s): Operating on copper work bench in 2.5-minute cycle mode.
Performance (pass/fail): Pass

Comments: No signal failures.

CE04 Testing configuration(s): Operating on copper work bench.
Performance (pass/fail): Fail

Comments: NB failure 0.7 to 7.5 dB over specifications in range 19.033 - 41.898 MHz.

Conducted Susceptibility Tests

CS02 Testing configuration(s): Operating on test bench, connected to test jig.
Performance (pass/fail): n/a

Comments: Unable to test because noise generated by the unit is greater than the test signal (unable to measure test signal).

CS06 Testing configuration(s): Operating on counter top.
Performance (pass/fail): Pass

Comments: Not susceptible to test spikes

Radiated Emissions Tests

RE02 Testing configuration(s): Operating on wooden test stand in the EMC chamber, ac and battery power.
Performance (pass/fail): Fail

Comments: ac operating failure data:
NB failures 0.2 to 46.8 dB over specifications in range 0.024 to 242 MHz; BB failures of 0.8 to 12.3 dB over specification in range 5.5 to 30 MHz.

Battery operating failure data:
NB failures 0.1 to 45.8 dB over specifications from 0.557 to 229.125 MHz; BB failures of 0.8 to 20.3 dB over specification in range 20.538 to 45.0 MHz.

Radiated Susceptibility Tests

RS03 Testing configuration(s): Operating on the wooden test stand in the EMC chamber, ac power only.
Performance (pass/fail): Fail

Comments: Susceptibility data:
0.89 - 6.68 V/m from 33.4 - 200 MHz
0.79 - 5.31 V/m from 200 - 332 MHz
5.01 - 7.50 V/m from 556 - 592 MHz

The temperature probe was placed in a cup of warm water with the mean temperature maintained from 89 to 106 degrees Fahrenheit.

3.3 CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

3.3.1 Criteria

Item No.	Criteria (source)	Remarks	Applicable subparagraph
1	The physical inventory is conducted solely for investigation and documentation.	n/a	2.1.2.1
2	The IVAC® Model 4000AEE will display consistent and accurate measurements.	met	2.1.2.2
3	Verify manufacturer's specified full power internal battery life expectancy of 2.5 hours or 150 blood pressure measurements.	met	2.2.2
4	The IVAC® Model 4000AEE will meet the limits established in NAFP 99 for electrical safety of medical equipment.	met	2.3.2
5	The IVAC® Model 4000AEE will be rated satisfactory in all major categories of the evaluation. These include: Visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.	partially met	2.4.2
6	The IVAC® Model 4000AEE will display consistent and accurate measurements while exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2
7	The IVAC® Model 4000AEE will remain operational and display consistent and accurate measurements while exposed to vibrational stresses.	met	2.6.2

8	The IVAC® Model 4000AEE will display consistent and accurate measurements during the high temperature operation check.	met	2.7.2.1
9	The IVAC® Model 4000AEE will display consistent and accurate measurements after the high temperature storage.	met	2.7.2.2
10	The IVAC® Model 4000AEE will display consistent and accurate measurements during the low temperature operation check.	met	2.8.2.1
11	The IVAC® Model 4000AEE will display consistent and accurate measurements after the low temperature storage.	met	2.8.2.2
12	The IVAC® Model 4000AEE will display consistent and accurate measurements while exposed to a high humidity.	met	2.9.2
13	The IVAC® Model 4000AEE will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.	partially met	2.10.2.1
14	The IVAC® Model 4000AEE will not malfunction when it is subjected to radiated fields as specified in MIL-STD-461A, Notice 4, paragraph 6.20.	partially met	2.10.2.2
15	The IVAC® Model 4000AEE will not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraphs 6.1 and 6.2.	partially met	2.10.2.3
16	The IVAC® Model 4000AEE will not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.	partially met	2.10.2.4

17	The flight surgeon will be able to operate the IVAC® Model 4000-AEE without physical or functional restrictions aboard the aircraft.	partially met	2.11.2.1
18	The IVAC® Model 4000AEE will not radiate EMI to disrupt or interfere with the other equipment or systems aboard the aircraft.	met	2.12.2.2
19	The aircraft will not radiate EMI to disrupt or interfere with the IVAC® Model 4000AEE.	met	2.12.2.3

3.3.2 Significant problems which require corrective action

Ambient noise levels during in-flight testing prevented proper reception and interpretation of Korotkoff sounds resulting in excess cuff pressures and errors in BP and heart rate measurements.

3.3.3 Suggested improvements

Microphone system in the BP cuff should be redesigned to improve operation in the aircraft noise environment.

3.4 REFERENCES

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3.4.3 Department of Defense. 1983. Environmental test methods and engineering guidelines. Washington, D.C. MIL-STD-810D. July.

3.4.4 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, D.C. TB 38-750-2. April.

3.4.5 Department of the Army. 1982. Environmental protection and enhancement. Washington, D.C. AR 200-1. June.

3.4.6 Underwriters Laboratory's, Inc. 1978. Standard for safety, medical and dental equipment. Chicago, Illinois. UL-544.

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3.4.8 Association for the Advancement of Medical Instruments. Human factors engineering guidelines and preferred practices for the design of medical devices. Arlington, Virginia. AAMI-HE-1988. February.

3.4.9 Department of the Army. 1978. Operator's manual, UH-60 and EH-60 helicopter, with changes 1-5. Washington, D.C. TM 55-1520-237-10. January.

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3.4.12 IVAC® Inc. Directions for use, vital check vital signs measurement system 4000 Series. San Diego, California. P/N 120713 NC.

3.4.13 Mitchell, G. W., and Adams, J. E. 1988. Technical test and evaluation of aeromedical equipment. Fort Rucker, AL: U.S. Army Aeromedical Research Laboratory. USAARL Letter Report LR-88-16-1-2.

3.5 ABBREVIATIONS

ac	alternating current
AEST	aeromedical equipment suitability test
AVSCOM	U.S. Army Aviation Systems Command
AWR	airworthiness release
BB	broadband
BP	blood pressure
BPM	beats per minute
CAAF	Cairns Army Airfield
CRT	cathode ray tube
dB	decibel
dc	direct current
ECG	electrocardiograph
EMC	electromagnetic compatibility
EMI	electromagnetic interference
fpm	feet per minute
GFE	government furnished equipment
Gpk	gravity, peak
G(rms)	gravity (root mean square)
Hz	hertz
IAW	in accordance with
ITOP	in-flight test operating procedure
IGE	in-ground effect
IVAC® Model 4000AEE	IVAC® Inc. vital check monitor
kg	kilogram
kHz	kilohertz
KIAS	knots indicated airspeed
lb	pound
LCD	liquid crystal display
LED	light emitting diode
LISN	line impedance stabilization network
MAP	mean arterial pressure
MEDEVAC	medical evacuation
MHz	megahertz
MIL-STD	military standard
mL	milliliter
mm	millimeter
mmHg	millimeters of mercury
MSL	mean sea level

NAFP	National Association of Fire Prevention
NB	narrowband
NBC	nuclear, biological, and chemical
NiCad	nickel cadmium
NOE	nap-of-the-earth
NVG	night vision goggle
RAM	random access memory
RF	radio frequency
RH	relative humidity
ROM	read only memory
TB	technical bulletin
TFT	technical feasibility testing
T & E	test and evaluation
UES	Universal Energy Systems, Inc.
USAARL	U.S. Army Aeromedical Research Laboratory
V/m	volts per meter

3.6 MANUFACTURERS' LIST

3.6.1 IVAC® Corporation
10300 Campus Point Drive
San Diego, CA 92121-1579

3.6.2 Sikorsky Aircraft
6900 Main Street
Stratford, CT 06601

3.6.3 Neurodyne-Dempsey, Inc.
200 Arrowhead Drive
Carson City, NV 89701

3.6.4 Tenney Engineering, Inc.
1090 Springfield Road
P.O. box 3142
Union, NJ 07083

3.6.5 Unholtz-Dickey Corporation
6 Brookside Drive
Wallingford, CT 06492

3.6.6 Solar Electronics Company
901 North Highland Avenue
Hollywood, CA 90038

3.6.7 Tektronix, Inc.
P.O. Box 500
Beaverton, OR 97077

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Fort Monmouth, NJ 07703-5304

Commander
10th Medical Laboratory
ATTN: Audiologist
APO New York 09180

Naval Air Development Center
Technical Information Division
Technical Support Detachment
Warminster, PA 18974

Commanding Officer, Naval Medical Research and Development Command
National Naval Medical Center
Bethesda, MD 20814-5044

Deputy Director, Defense Research and Engineering
ATTN: Military Assistant for Medical and Life Sciences
Washington, DC 20301-3080

Commander, U.S. Army Research Institute of Environmental Medicine
Natick, MA 01760

U.S. Army Avionics Research and Development Activity
ATTN: SAVAA-P-TP
Fort Monmouth, NJ 07703-5401

U.S. Army Communications-Electronics Command
ATTN: AMSEL-RD-ESA-D
Fort Monmouth, NJ 07703

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Naval Air Development Center
Warminster, PA 18974

Commander
Naval Air Development Center
ATTN: Code 602-B (Mr. Brindle)
Warminster, PA 18974

Commanding Officer
Harry G. Armstrong Aerospace Medical Research Laboratory
Wright-Patterson
Air Force Base, OH 45433

Director
Army Audiology and Speech Center
Walter Reed Army Medical Center
Washington, DC 20307-5001

Commander, U.S. Army Institute of Dental Research
ATTN: Jean A. Setterstrom, Ph. D.
Walter Reed Army Medical Center
Washington, DC 20307-5300

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Aberdeen Proving Ground, MD 21005

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U.S. Army Ballistic
Research Laboratory
ATTN: DRXBR-OD-ST Tech Reports
Aberdeen Proving Ground, MD 21005

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U.S. Army Medical Research
Institute of Chemical Defense
ATTN: SGRD-UV-AO
Aberdeen Proving Ground,
MD 21010-5425

Commander, U.S. Army Medical
Research and Development Command
ATTN: SGRD-RMS (Ms. Madigan)
Fort Detrick, Frederick, MD 21702-5012

Director
Walter Reed Army Institute of Research
Washington, DC 20307-5100

HQ DA (DASG-PSP-O)
5109 Leesburg Pike
Falls Church, VA 22041-3258

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Washington, DC 20375

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Adelphi, MD 20783-1197

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Analysis Agency
ATTN: AMXSY-PA (Reports Processing)
Aberdeen Proving Ground
MD 21005-5071

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and School Library
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Aberdeen Proving Ground, MD 21005

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Hygiene Agency
Building E2100
Aberdeen Proving Ground, MD 21010

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and Development Center
Aberdeen Proving Ground, MD
21010--5423

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U.S. Army Medical Research
Institute of Infectious Disease
SGRD-UIZ-C
Fort Detrick, Frederick, MD 21702

Director, Biological
Sciences Division
Office of Naval Research
600 North Quincy Street
Arlington, VA 22217

Commander
U.S. Army Materiel Command
ATTN: AMCDE-XS
5001 Eisenhower Avenue
Alexandria, VA 22333

Commandant
U.S. Army Aviation
Logistics School ATTN: ATSQ-TDN
Fort Eustis, VA 23604

Headquarters (ATMD)
U.S. Army Training
and Doctrine Command
Fort Monroe, VA 23651

Structures Laboratory Library
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NASA Langley Research Center
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Institute Library
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MacDill Air Force Base FL 33608

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(AUL/LSE)
Maxwell Air Fore Base, AL 36112

U.S. Air Force Institute
of Technology (AFIT/LDEE)
Building 640, Area B
Wright-Patterson
Air Force Base, OH 45433

Henry L. Taylor
Director, Institute of Aviation
University of Illinois-Willard Airport
Savoy, IL 61874

COL Craig L. Urbauer, Chief
Office of Army Surgeon General
National Guard Bureau
Washington, DC 50310-2500

Commander
U.S. Army Aviation Systems Command
ATTN: SGRD-UAX-AL (MAJ Gillette)
4300 Goodfellow Blvd., Building 105
St. Louis, MO 63120

U.S. Army Aviation Systems Command
Library and Information Center Branch
ATTN: AMSAV-DIL
4300 Goodfellow Boulevard
St. Louis, MO 63120

Federal Aviation Administration
Civil Aeromedical Institute
Library AAM-400A
P.O. Box 25082
Oklahoma City, OK 73125

Commander
U.S. Army Academy
of Health Sciences
ATTN: Library
Fort Sam Houston, TX 78234

Commander
U.S. Army Institute of Surgical Research
ATTN: SGRD-USM (Jan Duke)
Fort Sam Houston, TX 78234-6200

AAMRL/HEX
Wright-Patterson
Air Force Base, OH 45433

John A. Dellinger,
Southwest Research Institute
P. 0. Box 28510
San Antonio, TX 78284

Product Manager
Aviation Life Support Equipment
ATTN: AMCPM-ALSE
4300 Goodfellow Boulevard
St. Louis, MO 63120-1798

Commander
U.S. Army Aviation
Systems Command
ATTN: AMSAV-ED
4300 Goodfellow Boulevard
St. Louis, MO 63120

Commanding Officer
Naval Biodynamics Laboratory
P.O. Box 24907
New Orleans, LA 70189-0407

Assistant Commandant
U.S. Army Field Artillery School
ATTN: Morris Swott Technical Library
Fort Sill, OK 73503-0312

Commander
U.S. Army Health Services Command
ATTN: HSOP-SO
Fort Sam Houston, TX 78234-6000

Director of Professional Services
HQ USAF/SGDT
Bolling Air Force Base, DC 20332-6188

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Technical Library, Building 5330
Dugway, UT 84022

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Technical Library
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Aeromechanics Laboratory
U.S. Army Research and Technical Labs
Ames Research Center, M/S 215-1
Moffett Field, CA 94035

Sixth U.S. Army
ATTN: SMA
Presidio of San Francisco, CA 94129

Commander
U.S. Army Aeromedical Center
Fort Rucker, AL 36362

U.S. Air Force School
of Aerospace Medicine
Strughold Aeromedical Library Technical
Reports Section (TSKD)
Brooks Air Force Base, TX 78235-5301

Dr. Diane Damos
Department of Human Factors
ISSM, USC
Los Angeles, CA 90089-0021

U.S. Army White Sands
Missile Range
ATTN: STEWS-IM-ST
White Sands Missile Range, NM 88002

U.S. Army Aviation Engineering
Flight Activity
ATTN: SAVTE-M (Tech Lib) Stop 217
Edwards Air Force Base, CA 93523-5000

Ms. Sandra G. Hart
Ames Research Center
MS 262-3
Moffett Field, CA 94035

Commander, Letterman Army Institute
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USAAVNC (Building 602)
Fort Rucker, AL 36362-5021

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Building 602
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Dr. Garrison Rapmund
6 Burning Tree Court
Bethesda, MD 20817

Commandant Royal Air Force
Institute of Aviation Medicine
Farnborough Hants UK GU14 65Z
Dr. A. Kornfield, President
Biosearch Company
3016 Revere Road
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Dr. H. Dix Christensen
Bio-Medical Science Building, Room 753
Post Office Box 26901
Oklahoma City, OK 73190

Dr. Christine Schlichting
Behavioral Sciences Department
Box 900, NAVUBASE NLON
Groton, CT 06349-5900

Commandant
Academy of Health Sciences
ATTN: HSHA-COM (LTC Huether)
Fort Sam Houston, TX 78234

U.S. Air Force Armament
Development and Test Center
Eglin Air Force Base, FL 32542

COL Eugene S. Channing, O.D.
Brooke Army Medical Center
ATTN: HSHE-EAH-O
Fort Sam Houston, TX 78234-6200